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10/605,191

09/14/2003

Shyam K Gupta

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|-----------|---------------|
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3 MONTHS

01/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                          |  |                     |  |
|------------------------------|--------------------------|--|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>   |  | <b>Applicant(s)</b> |  |
|                              | 10/605,191               |  | GUPTA, SHYAM K      |  |
|                              | <b>Examiner</b>          |  | <b>Art Unit</b>     |  |
|                              | Lakshmi S. Channavajjala |  | 1615                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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### **DETAILED ACTION**

Claims 1-13 are pending in the instant application.

#### ***Claim Rejections - 35 USC § 112***

1. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claim recites luffa particles, which is a vague and ambiguous term. Applicants are requested to provide appropriate description as to what these particles are made of or their source.

Claim 9 recites the limitation "skin protective drug" in lines 1-2 . There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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2. Claim 2 is rejected under 35 U.S.C. 102(b) as being by anticipated by or over JP 06065036 (JP, abstract only).

JP discloses an oral composition for suppressing teeth coloring and sterilizing and removing microorganisms in the cavities comprising an organosilicone quaternary ammonium together with an alcohol such as ethanol. Thus, JP anticipates instant claim 2.

3. Claims 1, 2, 3, 8-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4, 525,343 to Raaf.

Raaf discloses a tooth and a mouth care agent in the form of toothpaste (meets instant claim 11), mouthwash, mouth spray or tooth powder etc., an anti-inflammatory agent, hesperidin ascorbate (abstract), which meets the instant anti-inflammatory of claim 1 and claim 8. In particular, example 3 and example 5 recite zeolite, which is sodium aluminum silicate and thus read on the instant divalent metal cation and zeolite anion pair. In addition the examples recite allantoin, carboxymethyl cellulose and silica, all of which read on the limitations of instant claim 1, 9, 10 and 13 respectively. Further, the above examples recite water that reads on the instant carrier base of claim 1.

4. Claim 2 is rejected under 35 U.S.C. 102(e) as being by anticipated by US 4,826,676 to Gioffre et al (Gioffre).

Gioffre discloses an anticariogenic and anticalculus composition comprising zeolitic zinc cations, a polishing agent, a source of fluoride ions (col. 2, L 21-30). The

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reference discloses a toothpaste composition comprising the zinc zeolite (last two lines of col. 2). Example 2 describes the aqueous solutions of the composition. Thus, Gioffre anticipates instant claim.

5. Claims 1-3, 10 and 12-13 are rejected under 35 U.S.C. 102(e) as being by anticipated by US 6,638,521 to Dobrozsi.

Example 6 of Dobrozsi shows a pharmaceutical composition comprising natural honey (reads on anti-inflammatory), sodium saccharin (sugars), magnesium aluminum silicate clay, natural menthol and oil of eucalyptus (both read on anti-inflammatory agents as well as plant extracts), water (instant carrier) and other components. Thus, Dobrozsi anticipates instant claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,525,343 to Raaf.

Raaf does not expressly state if the composition is in the form of an emulsion or microemulsion or suspension etc. However, depending on the components of the

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composition, preparing an appropriate emulsion or suspension that is suitable for delivery i.e., as toothpaste or a mouth care composition is routinely practiced in the art. Hence it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to choose an appropriate form of preparing toothpaste or other oral care composition without affecting the efficacy of the individual components of the composition.

7. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4, 525,343 to Raaf in view of US 4,826,676 to Gioffre et al (Gioffre).

Instant claims are directed to a zeolite anion pair wherein the metal cation is chosen from magnesium, zinc etc. Raff, discussed above, fails to teach a toothpaste with the claimed cations and instead a sodium alumiosilicate.

Gioffre, discussed above, teaches zinc-zeolite in a toothpaste composition for good polishing and abrasive effects. The composition of Gioffre is also in the form of toothpaste and comprises components such as fluoride compounds, cellulose, silica etc., similar to that of Raaf. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add zinc zeolite of Gioffre in the composition of Raaf because both the references are directed to tooth paste compositions contains fluoride antimicrobials and alumiosilicate compounds and because Gioffre suggests that zinc zeolite ion exchange pair is not only biologically active but also is an excellent abrasive and a polishing agent to remove dental plaque. Therefore, a skilled artisan

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would have expected to impart the above dental plaque abrasive and polishing effect to the toothpaste composition of Raaf by adding the zinc zeolite ion pair of Gioffre.

8. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4, 525,343 to Raaf, as applied to claims 1-3, 8-11 and 13 above, and further in view of JP 06065036.

Raaf discussed above, fails to teach the claimed quaternary ammonium cation and zeolite ion pair in the toothpaste composition. Raaf instead teaches a sodium zeolite (examples).

JP discussed above teaches toothpaste and other oral care compositions comprising organosilicone quaternary ammonium together with an alcohol such as ethanol. JP suggests that the quaternary ammonium zeolite is very effective in suppressing the teeth coloring, sterilizing and removing microorganisms in the oral cavity and also in manifesting plaque control. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add the quaternary ammonium zeolite of JP in the toothpaste composition of Raaf because of the above benefits to the teeth and oral cavity described JP. A skilled artisan would have expected to reduce inflammation as well as provide protection from plaque, microorganism and teeth coloring.



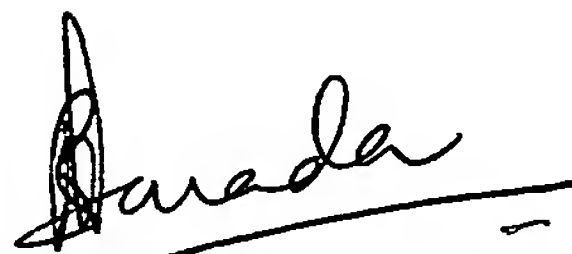
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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December 29, 2006

  
LAKSHMI S. CHANNAVAJJALA  
PRIMARY EXAMINER



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